Medical Device Legislation: Its Professional Implications —

By Reed M. Gardner, Ph.D.*

After several years of consideration in Congress, medical device legislation became law (PL 94-295) on May 28, 1976. This law, to be administered by the Food and Drug Administration (FDA), will have a significant impact on the design, manufacture, and distribution of medical equipment—its impact on the health care provider and the health care professional is less apparent. However, there are significant new responsibilities, possible limitations, and, hopefully, benefits to be gained from the new law by these professionals. To point up these factors, a brief review of the historical background of the FDA and its regulatory authority will be useful.

The early colonists, realizing the importance of having high quality food products, set up an evaluation system to ensure the quality of tea, wheat, etc. Regulation of foods and drugs was primarily a states rights issue until 1906, when the original Federal Food and Drug Statute was enacted. The primary concern of this law was to keep adulterated and misbranded drugs out of interstate commerce. The 1906 act was weak in that it required no pre-market safety testing and no effectiveness evaluation. It took the "Elixir of Sulfanilamide" disaster in 1938, in which more than 100 people died, to stimulate further legislation. This disaster, with its negative press coverage, resulted in Congress enacting the legislation establishing the FDA in 1938. The result was a more stringent regulation on manufacture of drugs in order to assure their safety by pre-market clinical trials. However, the 1938 law required no demonstration of effectiveness of drugs. It took the "thalidomide" disaster in Europe in 1962 to bring the public and Congress to the decision that drugs used for investigational purposes needed to be pre-market tested for both safety and effectiveness. Thus, the 1962 amendment to the 1938 law.

Notice the reaction of Congress to each of these disasters. First, there was a problem; secondly, the problem was widely covered by the press, who cried that the public should be protected; then Congress enacted legislation that increased FDA's authority to protect the public.

Another Call for Congressional Action

The past three decades have seen a proliferation of a variety of types of medical devices, some of which have caused serious injury or death to patients, and others of which have saved lives. The medical device failures came under the scrutiny of the press, the public, and Congress, and, as a result, after several years of deliberations and hearings Congress enacted the legislation which has become known as the Medical Device Amendment of 1976.

According to the law, "the term 'device' means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; 2) intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or 3) intended to effect the structure of any function of the body of man or other animal and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal purposes." This quotation from the legislation gives an example of the language of the legislation, which is some 45 pages long. The definition of a "device" has significant implications. For example, there are some drugs which will now become devices. The orderly transition from drugs to devices is outlined in the legislation.

Device Classifications

A primary element of the legislation calls for an orderly classification of devices. There are three specific classes†: Class I is *general control*. Devices in this class are those that are not used in supporting or sustaining human life and that don't carry a potential unreasonable risk of illness or injury. A Class II device must meet *performance standards* which must be established in order to provide reasonable assurance of the safety and effectiveness of the device. Class III is *pre-market approval*. These devices do not fit into either of the other classes and are designed for use in supporting or sustaining human life or in preventing impairment of human health; they may carry a potential unreasonable risk of illness or injury.

The classification of devices will be the job of the Secretary of Health, Education and Welfare (HEW) and will be d primarily by panels which are given year from the enactment of the legislat to classify all medical devices into on the three classes. Therefore, the pa have considerable scientific and polit power.

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Scientific groups are given authority nominate members to the panels. American Thoracic Society currently Dr. Earle B. Weiss serving and will s have Dr. Philip C. Hopewell from Francisco serving on the Pulmonary S committee of the Anesthesiology Pa We are also working to get a sepa panel set up for pulmonary funct equipment.

Unless otherwise specified, a device automatically be classified Class III. Secretary of HEW can at any time cha a device classification based on hear or other information available to him. can classify a device as Class II while formance standards, including specif tions for construction, testing, label and measuring device performance, being developed.

The law requires periodic evaluation a updating of device classifications by panels. The FDA will look to standa setting organizations for updating. It be possible for voluntary organizatio such as ATS to propose standards to FDA. Input from voluntary and standa organizations is provided for in the and is welcomed by the staff of the Me cal Devices Bureau of the FDA. This reau is very interested in voluntary co erative standards' establishing arran ments with any organization, especia professional groups. Before it can applied, a standard must be published the Federal Register. Since this is no scientific journal and does not have wide readership that *American Review Respiratory Disease* does, the staff ATS and the Medical Devices Commit will try to keep readers informed on ite

*Chairman, Medical Devices Committee.

†For a detailed description of the three classes, see Schmidt, A.: Medical device legislation, ATS News, Summer 1976, *2*, p. 16.

"The Secretary of HEW can at any time change a device classification based on hearings or other information available. . . . The FDA will look to standard-setting organizations for updating. It will be possible for voluntary organizations such as ATS to propose standards. . .
". . . .Most of the burden of the legislation, currently on the manufacturer, will soon shift to the professionals."

relating to the medical devices legislation through the ATS NEWS. For readers who have a personal interest and who are involved in device testing and evaluation, it will be necessary to personally review the device legislation and the appropriate sections of the Federal Register in order to understand the rulings on individual devices.

Those scientists and investigators working with institutions would be wise to consult their institutional legal officers before getting involved in the development of a new "device." (Appropriate publications and their sources are listed below).

Those products which were manufactured and sold in interstate trade before May 28, 1976, will not be controlled under the device legislation for a period of at least three years. During that time period, panels will classify devices and standards will be developed for them. The primary impact of the legislation, at the moment, is on the manufacturer who must immediately get pre-market approval before a new product can be tested. The manufacturer also will be required to register all medical devices. A product development protocol must be outlined very carefully in order for it to receive FDA approval. There is a chance that this procedure will have a deleterious economic impact on the manufacturers, "but the Commissioner of the Food and Drug Administration has determined that this will not likely cause a significant economic impact."

Advisory committees, rather than review panels, will review medical devices for pre-market approval. Although banned devices may be removed from the market by the HEW Secretary, there is a provision for judicial review of such cases.

The HEW Secretary may issue a "recall" order to assure that adequate notification is provided in order to eliminate risk to all health professionals or lay persons who prescribe or use a device. Recall orders "shall require that the health professionals who prescribe or use the device, provide notification of the individuals whom the health professional treated with the device of the risk presented by the device and of any action which may be taken by or on behalf of such an individual to eliminate or reduce such risk." Details of the recall procedure and of repair, replacement, or refund for defective devices are outlined in the legislation.

The primary burden for reporting and keeping records on devices rests on the manufacturer, not the physician. Practitioners are specifically exempt from detailed record keeping when the device is used solely in research and teaching, not for sale. Details of the implementation of record keeping will await action by the FDA in setting up its specific policies. Class I devices will be exempt from record keeping and reporting.

Custom devices, particularly those intended to meet the special needs of physicians or dentists or other specially qualified persons, are specifically excluded from legislative controls. Trade secrets are guaranteed.

The Secretary of HEW may by regulation require that a device be restricted to sale, distribution, or use only upon written or oral authorization of a practitioner licensed by law to administer or use such a device, or upon such other conditions as the Secretary may prescribe in such regulation.

All devices will be required to meet good manufacturing practice standards, which will be established by a group specified by the law to represent government, manufacturers, practitioners, and the public.

Investigational devices are exempted from the law for the purpose of encouraging to the extent consistent with the protection of the public health and safety, discovery and development of useful devices intended for human use. The FDA has been given 120 days starting from the enactment of legislation to set up the procedures and conditions. The form for this has been proposed in the August 20, 1976 Federal Register. The primary approved elements of investigational device experimentation are (*1*) that a request will have to be made to the FDA for approval by a local "approved investigational committee," which can be the same committee as those used now for approving human subjects related research for NIH; (*2*) that a request must then be sent to the FDA outlining the research plan; and (*3*) that within 30 days after the FDA has received the request, if it is not denied, it is automatically approved for investigational use. In general, animal testing will not require FDA approval, and in many cases it will be valuable to do before submitting a request for approval.

The HEW Secretary is required to release safety and effectiveness information on devices in order to keep the public properly informed. The safety of a device cannot be established by comparing it with another device; rather, it must be approved on the basis of its own merits.

State and local rules may not differ, except by application to the Secretary of HEW; in any case, the local rules must be more stringent than the Federal rules, as may be dictated by local conditions.

Conclusion

The intent of Congress in establishing the medical device legislation was to improve the safety and effectiveness of medical devices and to ban those that are unsafe and ineffective. Most of the burden of the legislation, currently on the manufacturer, will soon shift to the professionals. Professional organizations must soon establish safety standards for several types of currently used medical devices. Eventually the answers to the question of what the risk-benefit ratio is will have to be explored not only by device manufacturers but also by research and clinical investigators.

ATS will attempt to keep its membership informed on this important legislation since it will affect all practitioners, scientific investigators, and others who are involved in the delivery of health care.

The legislation passed with minimal concern by manufacturers, practitioners, or professional organizations, and we should be prepared as individuals and as a professional organization to support it and help achieve its goals, rather than fight its implementation. Those areas where improvements are needed should be handled in a positive, straightforward manner where possible, and, where necessary, should be challenged in the courts.

Note: The above review is intended for information only. Legal decisions should be made only after careful evaluation of the documents listed below.

Reference Documents

1. Public Law 94-295 "Medical Device Amendments of 1976."
2. Federal Register - August 12, 1976 - Medical Devices Performance Standards Activities.
3. Federal Register - August 20, 1976 - Medical Devices - Proposed Investigational Device Exemptions.

Source: All of the above obtainable from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402.